

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/23090

<b>A. CLASSIFICATION OF SUBJECT MATTER</b>												
IPC(7) : C12N 15/00,15/09,15/63,15/70,15/74												
US CL : 435/320.1												
According to International Patent Classification (IPC) or to both national classification and IPC												
<b>B. FIELDS SEARCHED</b>												
Minimum documentation searched (classification system followed by classification symbols) U.S. : 435/320.1												
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched												
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Please See Continuation Sheet												
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>												
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.										
X	ANTON et al. Site-specific recombinant mediated by an adenovirus vector expressing the Cre recombinase protein: a molecular switch for control of gene expression. Journal of Virology. August 1995, Vol. 69, No. 8, pages 4600-4606, see entire document.	1,7,10,11,12,22										
X	US 6,225,121 B1 (SAVAKIS et al.) 01 May 2001 (01.05.2001), column 11, lines 21-54, see whole document.	1,7,8,20,22										
X,P	US 2002/0103152 A1 (KAY et al.) 01 August 2002 (01.08.2002); pages 2-8, see whole document.	1,7,8,9,21,22										
X,P	US 2002/0132350 A1 (SUZUKI et al.) 19 September 2002 (19.09.2002), pages 2-9,15-17, see whole document.	1,3,5,7,13,14										
X,P	US 6,461,864 B1 (SORIANO et al.) 08 October 2002 (08.10.2002), columns 2-3 and 13-15, see whole document.	1,7,10,11,12,20,21,22,23,24										
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.												
* Special categories of cited documents: <table border="0"> <tr> <td>"A" document defining the general state of the art which is not considered to be of particular relevance</td> <td>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</td> </tr> <tr> <td>"E" earlier application or patent published on or after the international filing date</td> <td>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</td> </tr> <tr> <td>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</td> <td>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</td> </tr> <tr> <td>"O" document referring to an oral disclosure, use, exhibition or other means</td> <td>"Z" document member of the same patent family</td> </tr> <tr> <td>"P" document published prior to the international filing date but later than the priority date claimed</td> <td></td> </tr> </table>			"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention	"E" earlier application or patent published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art	"O" document referring to an oral disclosure, use, exhibition or other means	"Z" document member of the same patent family	"P" document published prior to the international filing date but later than the priority date claimed	
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"P" document published prior to the international filing date but later than the priority date claimed												
Date of the actual completion of the international search 12 January 2004 (12.01.2004)		Date of mailing of the international search report 02 APR 2004										
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230		Authorized officer Brian Whiteman Telephone No. (703) 308-0196										

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**BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING**

This International Search Authority has found 5 inventions claimed in the International Application covered by the claims indicated below:

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claim(s) 1-9, 15, 16, 18, 19-23, 25 and 26, drawn to a composition comprising a nucleic acid comprising a transgene flanked by two terminal repeats and a nucleic acid encoding a transposase under the control of a promoter element.

Group II, claim(s) 1-7, 10, 11, 12, 15, 17-20, 23, 25, and 26 drawn to a composition comprising a nucleic acid comprising a transgene flanked by two terminal repeats and a nucleic acid encoding a recombinase under the control of a promoter element.

Group III, claim(s) 1-7, 13, 14, 15, 18, 19, 20, 23-26, drawn to a composition comprising a nucleic acid comprising a transgene flanked by two terminal repeats and a nucleic acid encoding an integrase under the control of a promoter element.

Group IV, claim(s) 1-7, 15, 18, 19, 20, 23, 25, and 26, drawn to a composition comprising a nucleic acid comprising a transgene flanked by two terminal repeats and a nucleic acid encoding an integron under the control of a promoter element.

Group V, claim(s) 1-7, 15, 18, 19, 20, 23, 25, and 26, drawn to a composition comprising a nucleic acid comprising a transgene flanked by two terminal repeats and a nucleic acid encoding a terminase under the control of a promoter element.

1. This International Searching Authority considers that the international application does not comply with the requirements of unity of invention (Rules 13.1, 13.2 and 13.3) for the reasons indicated below:

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-V appear that they all relate to a composition comprising a nucleic acid comprising a transgene flanked by two terminal repeats and a nucleic acid encoding an integrating enzyme under the control of a promoter element. However, US 6,225,121 B1 (01 May 2001) teaches a vector comprising a Minos transposable element and DNA encoding the transposase protein, and can be modified to include a nucleic acid sequence (e.g., indicator gene) flanked by the inverted terminal repeats of the isolated transposable element.

Therefore, the technical feature linking the inventions of groups I-V does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The special technical feature of Group I is considered to be a composition comprising a nucleic acid comprising a transgene flanked by two terminal repeats and a nucleic acid encoding a transposase under the control of a promoter element.

The special technical feature of Group II is considered to be a composition comprising a nucleic acid comprising a transgene flanked by two terminal repeats and a nucleic acid encoding a recombinase under the control of a promoter element.

The special technical feature of Group III is considered to be a composition comprising a nucleic acid comprising a transgene flanked by two terminal repeats and a nucleic acid encoding an integrase under the control of a promoter element.

The special technical feature of Group IV is considered to be a composition comprising a nucleic acid comprising a transgene flanked by two terminal repeats and a nucleic acid encoding an integron under the control of a promoter element.

The special technical feature of Group V is considered to be a composition comprising a nucleic acid comprising a transgene flanked by two terminal repeats and a nucleic acid encoding a terminase under the control of a promoter element.

Accordingly, Groups I-V are not so linked by the same or a corresponding technical feature as to form a single inventive concept.

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## Continuation of B. FIELDS SEARCHED Item 3:

WEST2.1, STN

search terms: terminal repeat, integrating enzyme, promoter, transposase, integrase, recombinase, integron, terminase, nucleic acid, transgene, heterologous

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**Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)**

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claim Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claim Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claim Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)**This International Searching Authority found multiple inventions in this international application, as follows:  
Please See Continuation Sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest ☐ The additional search fees were accompanied by the applicant's protest.  
☐ No protest accompanied the payment of additional search fees.

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